

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1-12, 20-42 and 55-72 are canceled in view of applicant's response filed 4 March 2008. Therefore, claims 13-19 and 43-54 are currently under examination.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Merchant et al. US 6,221,176 B1(Merchant).

The rejection for instant claims 13-14 is maintained for the same reasons as stated in paragraph 4 of the previous Non-Final Office Action mailed 31 October 2007.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 13-17 and 43-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heimann et al. US 5,938,976(Heimann).

The rejection for instant claims 13-17 and 43-54 is maintained for the same reasons as stated in paragraph 6 of the previous Non-Final Office Action mailed 31 October 2007.

6. Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heimann and further in view of Sako et al. US 2003/0213533 A1(Sako).

The rejection for instant claims 18-19 is maintained for the same reasons as stated in paragraph 7 of the previous Non-Final Office Action mailed 31 October 2007.

### ***Response to Arguments***

7. Applicant's arguments filed 4 March 2008 have been fully considered but they are not persuasive.

In the remarks, applicant argues that the preamble is tied to the "implantable device" expressly set forth in the body of the patent claim and gives "meaning and vitality" to the claim. In addition, applicant argues that the sodium nitrate as claimed is an integral part of the amorphous oxide layer of the implantable device.

The examiner does not find applicant's argument persuasive because the instant claims are directed to a passivation solution, not an amorphous oxide covered implantable device. The preamble "for forming an amorphous oxide layer over an implantable device" describes the intended use for the claimed passivation solution, and it does not limit the structure of the claim invention because it does not include any limitations that materially affect the composition of the claimed passivation solution.

The language "wherein said sodium nitrate provides oxygen in the formation of said amorphous oxide layer over the implantable device" in the body of the claim merely

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describes the function of the claimed sodium nitrate when the claimed passivation solution is applied to an implantable device. However, it does not materially affect the claimed passivation solution. The rejection ground is proper if the sodium nitrate in the passivation solutions of the prior art references are capable of providing oxygen to form the amorphous oxide layer on an implantable device. In this regard, since the treatment solution of Merchant contains the same pH buffer and sodium nitrate as claimed, one of ordinary skill in the art would also find the sodium nitrate in the passivation solution of Merchant capable of providing oxygen to form an amorphous oxide layer over a metallic implantable device. Heimann teaches that its treatment solution produces an amorphous oxide layer on the surface of a metal substrate (abstract, col. 2 lines 62-67), such as Co, Cr, Ti, steel, Zr metals and alloys thereof (col. 5 lines 53-61). Since the implant device of the instant invention is made of the same types of metals, the passivation solution of Heimann is also capable of forming the claimed amorphous layer on an implant device as claimed. Therefore, the examiner maintains that the rejection grounds are proper.

Furthermore, applicant argues that none of the prior art references teach the claimed implantable device and the coating of the references are intended for use outside the human body.

Again, applicant's argument is directed towards the intended use of the claimed invention as well as the intended use of the prior art references. The difference in the intended use for the prior art passivation solutions does not materially affect the composition of the passivation solutions. Since applicant has not provided factual

evidence data demonstrating the prior art passivation solutions are not capable of forming the claimed amorphous oxide layer on a implant device, the examiner maintains that the rejection grounds are proper.

***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lois Zheng whose telephone number is (571) 272-1248. The examiner can normally be reached on 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King can be reached on (571) 272-1244. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Roy King/  
Supervisory Patent Examiner, Art  
Unit 1793

LLZ  
6/3/08